K030507

MAY 2 0 2003

510(k) SUMMARY

Statement:	This summary of 510(k) substantial equivalence is being submitted in accordance with the requirements of 21 CFR 807.92 and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.
Submitter's Identification:	VisionQuest Industries, Inc. 18011 Mitchell South Irvine, CA 92614 Contact Person: Alan Wade, Director, Product Development Phone: (949) 261-3000 Fax: (949) 477-9672
Date Summary Prepared:	February, 12, 2003
Name of the Device:	Proprietary Name: T.E.A.R. Tech3 Common Name: Interferential Stimulator High Volt Pulsed Current Stimulator Neuromuscular Electrical Stimulator
Classification Name:	Interferential Current Therapy (LIH) Stimulator, Muscle, Powered (IPF)
Predicate Device Name:	Surgi Stim 510(k) Number: K982388 VisionQuest Industries, Inc., 18011 Mitchell South, Irvine, CA 92614 Jace Tri-Stim 510(k) Number: K931781 Thera-Kinetics DBA Jace Systems 7 Carnegie Plaza, Cherry Hill, NJ 08003

Device Description:

The T.E.A.R. Tech3 IF/Muscle Stimulator is a combination device combining the functionality of Interferential (IF) / Neuromuscular (NMES) and High Volt Pulsed Current (HVPC) stimulators in one device which produces a mild electrical current that is

transmitted via leads to electrodes placed on the skin in areas predetermined by the clinician. The device, a set of electrodes with leads, a battery pack (lithium ion rechargeable and alkaline), carrying case, and instructions for use make up the T.E.A.R. Tech3 stimulation system.

Indications for Use:

The High Volt Pulsed Current Stimulator and Neuromuscular Electrical Stimulators share the same indications for use as listed below:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increases local blood circulation
- Promotes muscle re-education and range of motion
- Maintaining and increasing range of motion
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Interferential Stimulators have one additional indication for use:

- Provides symptomatic relief and management of post surgical, acute, or chronic pain

The target population for this device is patients with chronic, acute pain syndrome, and/or recovering from orthopedic related surgery.

Comparison to Predicate Devices:

The modified device has the same technological characteristics as the predicate devices. The form, fit, function and method of operation are similar.

Conclusion:

The T.E.A.R. Tech3 has the same intended use and technological characteristics as the predicate devices. No new questions of safety or effectiveness have been raised; therefore the T.E.A.R. Tech3 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 0 2003

Mr. Alan Wade
Director, Product Development
VisionQuest Industries, Inc.
18011 Mitchell South
Irvine, California 92614

Re: K030507
Trade/Device Name: T.E.A.R. Tech3, Model # 44TT03
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Codes: IPF and LIH
Dated: February 13, 2003
Received: February 19, 2003

Dear Mr. Wade:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, M.D., Ph.D.
Director
Division of General, Restorative, and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

The T.E.A.R. Tech3 IF/Muscle Stimulator is a combination device and has the same indications for use as two different types of predicate devices.

The High Volt Pulsed Current Stimulator and Neuromuscular Electrical Stimulators share the same indications for use as listed below:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increases local blood circulation
- Promotes muscle re-education and range of motion
- Maintaining and increasing range of motion
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Interferential Stimulators have one additional indication for use:

- Provides symptomatic relief and management of post surgical, acute, or chronic pain

The target population for this device are patients with chronic, acute pain syndrome, and/or recovering from orthopedic related surgery.

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030507